NC DHHS COVID-19 Bi-Weekly LHD Webinar

February 22, 2022

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

A VIAL IN EVERY FRIDGE

Opening Remarks & Leadership Update

Opening Remarks & Leadership Update	**Beth Lovette, RN, BSN, MPH** Deputy Director/Section Chief Local and Community Support
Epi Picture	**Zack Moore, MD, MPH** State Epidemiologist and Epidemiology Section Chief
Policy	**Elizabeth Cuervo Tilson, MD, MPH** State Health Director Chief Medical Officer
Vaccine Update	**Ryan Jury, RN, MBA** COVID-19 Vaccine Program Director
Therapeutics	**Tim Davis, PharmD, BCNP, PMP** Medical Countermeasures Coordinator

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QUESTIONS?
Please use the Zoom Q&A function or email your questions to: questionsCOVID19webinar@gmail.com

Epi Picture

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Vaccine Update

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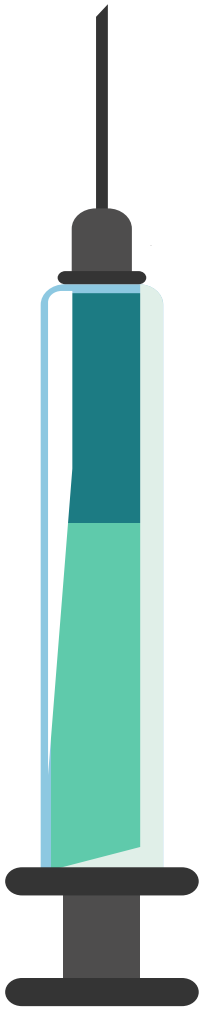
CDC GUIDANCE UPDATES FOR IMMUNOCOMPROMISED INDIVIDUALS



CDC GUIDELINE CHANGES FOR IMMUNOCOMPROMISED INDIVIDUALS

NEW: People who received J&J should receive a total of 3 doses:

1 J&J dose,
+
1 additional mRNA dose at least 28 days later,
+
1 booster dose at least 2 months after the 2nd dose.

NEW: People who received a 3-dose mRNA COVID-19 vaccination series should receive the booster dose 3 months after the primary series.

CLARIFY: Those who received Pfizer-BioNTech or Moderna should receive a total of 4 doses:

a primary series of 3 doses of an mRNA vaccine
+
1 booster dose of an mRNA vaccine (4th dose).

Other CDC Clinical Updates Include:

- It is no longer necessary to delay COVID-19 vaccination following receipt of monoclonal antibodies or convalescent plasma.
- Updated guidance on receiving a booster dose if vaccinated outside the United States.
- Updated contraindication and precaution section to include history of myocarditis or pericarditis after an mRNA COVID-19 vaccine.

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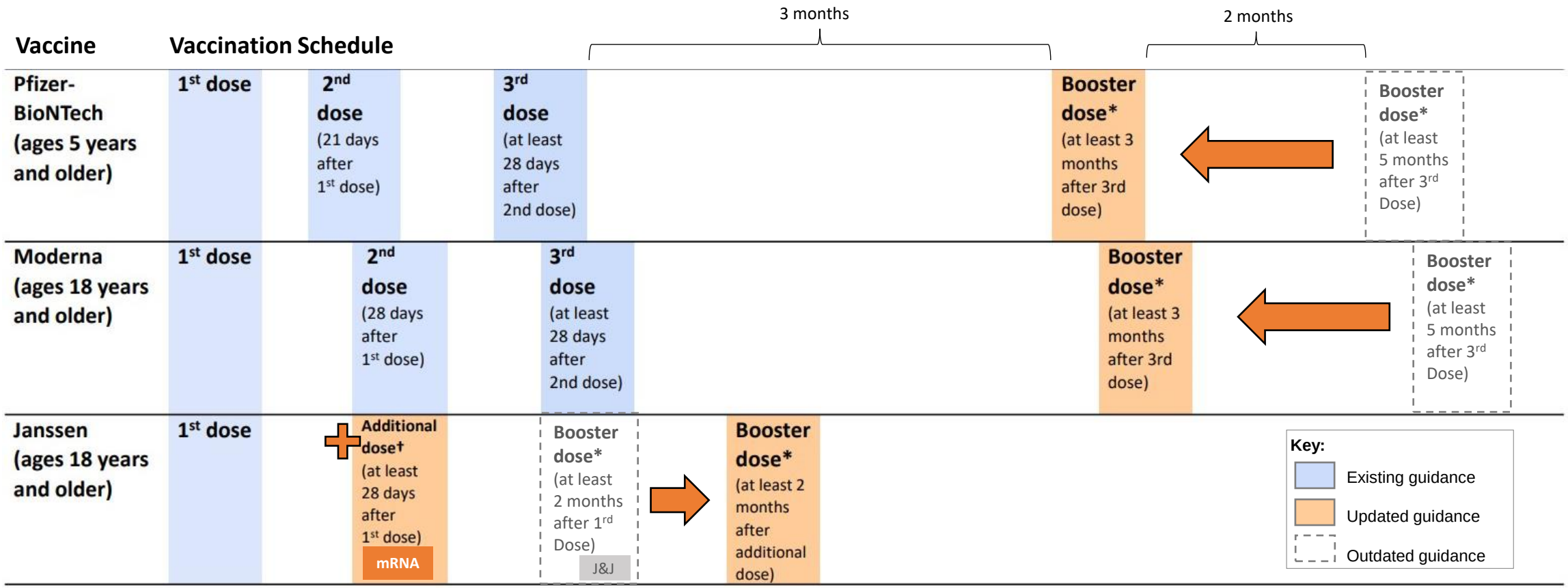
The latest versions of all Statewide Standing Orders can always be found here.

MODERATELY OR SEVERELY IMMUNOCOMPROMISED – REVISED BOOSTER SCHEDULE

Key Takeaways:

— Pfizer & Moderna Booster Interval shortened to 3 months after 3rd Dose for Immunocompromised populations

— Additional (mRNA) dose recommended after Janssen primary series

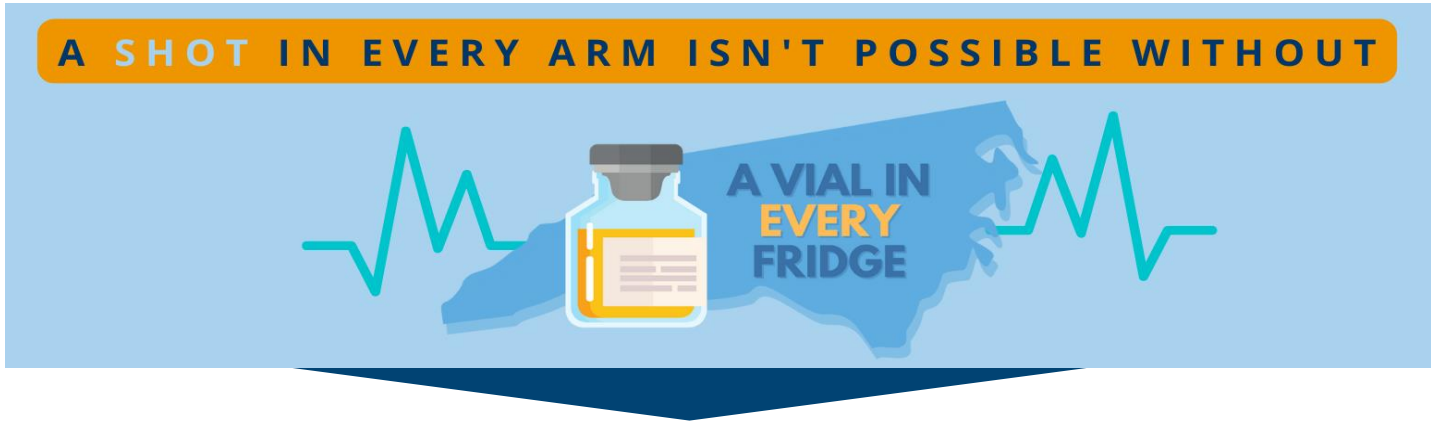


*Any COVID-19 vaccine can be used for the booster dose in people ages 18 years and older, though mRNA vaccines are preferred. For people ages 12–17 years, only Pfizer-BioNTech can be used. People ages 5–11 years should not receive a booster dose.

†Only Pfizer-BioNTech or Moderna COVID-19 Vaccine should be used

Source: CDC

WHAT WE'RE DOING: A VIAL IN EVERY FRIDGE



Moving from mass vaccination⟶vaccine everywhere to reduce missed opportunities

Ensuring we never miss an opportunity to vaccinate

77%

% of parents say they trust their child's **pediatrician** to provide **reliable information** on vaccines for children*

44%

% of the unvaccinated that would feel **most comfortable** getting vaccinated at their **doctor's office****

46%

% of parents with an unvaccinated child aged 5-11 who say hearing from people they trust would make them much more likely to get their child vaccinated

100%

Of locations with vaccine on hand = 0% missed opportunities to counsel, validate, and vaccinate

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BRIEF OVERVIEW: VACCINE UPDATES

LTC Booster

- Current NC SNF resident booster rate at 73%, above national average of 68%
- Current NC Non-SNF Resident Booster Rates reported via Survey Outreach at 82% (362 Unique Responses from Facilities)
- Conducting Help Desk phone and email outreach aiding in vaccination data validation for LTCFs as well as partnership LTCFs with Vaccine Vendors

FDA/CDC Updates

- Revised booster schedule and guidance updates for moderately or severely immunocompromised
  - Pfizer & Moderna Booster Interval shortened to 3 months after 3rd Dose for Immunocompromised populations
  - Additional (mRNA) dose recommended after Janssen primary series
- Updated CDC guidance for those outside the US

Vial in Every Fridge

- Moving from the idea of mass vaccination to reducing missed opportunities by offering vaccine
- Currently 72.9% of total VFC providers are enrolled, very close to our goal of 80%
- Looking into additional levers for provider recruitment, discussions with non-traditional associations

Therapeutics

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BEBTELOVIMAB

EUA issued by FDA on February 11th

Authorization

- Treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40kg):
  - With positive COVID-19 test (of any kind)
  - Who are at high risk for progression to severe COVID-19
  - For whom alternative COVID-19 treatment options approved or authorized by the FDA are not accessible or clinically appropriate

Mechanism of Action

- Monoclonal antibody that binds to the SARS-CoV-2 spike protein and blocks attachment to human cells

Dosage and Administration

- 175mg administered as a single IV injection over at least 30 seconds, followed by 1 hour of observation
- Must be administered as soon as possible after positive COVID-19 test and within **7 days** of symptom onset

Storage and Handling

- Must be stored in a refrigerator at 2°C to 8°C (36°F to 46°F)

THERAPEUTICS OVERVIEW

Monoclonal antibodies, or mAbs, are antibodies made in a laboratory to fight a particular infection. The Food and Drug Administration (FDA) has issued **Emergency Use Authorization (EUA)** for the use of monoclonal antibody therapies for adult and pediatric patients aged 12 and older. mAbs are given to patients with an infusion, subcutaneous injection, or intramuscular injection. They are used for treatment or prevention. There are three mAb products currently authorized for use that are effective against the SARS-CoV-2 Omicron variant:

mAbs Generic Name	Also known as	Authorized Indication	Route of Administration	Dosing Regimen	Authorized Patient Population	Standing Order?*	Efficacy
Sotrovimab	**Sotrovimab**	COVID-19 Treatment **within 10 days** of symptoms	Intravenous Infusion	500 mg of sotrovimab	Patients aged **12 years and older** and weighing at least 40 kg	Yes, revised February 15th	**79% effective** in preventing hospitalization or death. Retains efficacy against Omicron. In-vitro data suggests some reduced efficacy against BA.2 subvariant. Clinical impacts unknown at this time
Bebtelovimab	**Bebtelovimab**	COVID-19 Treatment **within seven (7) days** of symptoms	Intravenous Infusion	175 mg of bebtelovimab	Patients aged **12 years and older** and weighing at least 40 kg	Yes, as of February 15th	Placebo controlled trial data not available to determine % effectiveness at reducing hospitalization. Retains efficacy against both the omicron variant and the BA.2 omicron subvariant
Tixagevimab / cilgavimab	**EVUSHELD AZD7442**	Pre-exposure prophylaxis (PrEP)	Intramuscular Injection	Two simultaneous IM injections every six (6) months	Patients aged **12 years and older** who are immunocompromised or have a contraindication for COVID-19 vaccines	No – per FDA/HHS	**77% effective** in preventing SARS-CoV-2 RT-PCR symptomatic illness Retains efficacy against Omicron

**Per the Public Readiness and Emergency Preparedness Act, pharmacies were added to the eligible providers and can now administer monoclonal antibody treatment*
Note: the EUAs for REGEN-COV and Bamlanivimab and Etesevimab are paused due to ineffectiveness against the Omicron variant

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THERAPEUTICS OVERVIEW

The FDA has issued **EUAs** for the use of oral antiviral therapies for adult and pediatric patients aged 12 and older (molnupiravir authorized for 18+ only). Oral antivirals are administered orally and only used for treatment. There are two (2) types of oral antivirals that have been authorized for use for COVID-19. Both therapeutics target mild-to-moderate COVID-19 in individuals who are at risk of severe illness:

Generic Name	Also known as	Authorized Indication	Route of Administration	Administration Requirements	Dosing Regimen	Authorized Patient Population	Standing Order?	Efficacy
Molnupiravir	**MK-4482, Merck**	Treatment of mild-to-moderate COVID-19 in adults who are at risk for progressing to severe COVID-19 and for whom alternate treatment is not accessible or clinically appropriate	Oral	Must start **within five (5) days** of symptom onset Not recommended during pregnancy	800 mg twice-daily for five (5) days	Adult patients aged 18 years and older	No – per FDA/HHS	**30% effective** in preventing hospitalization or death when started within five (5) days of symptom onset Retains efficacy against Omicron
Paxlovid	**Nirmatrelvir / Ritonavir, Pfizer**	Treatment of mild-to-moderate COVID-19 in adult and pediatric patients (12+) who are at risk for progressing to severe COVID-19	Oral	Must start **within five (5) days** of symptom onset Dosage adjustment required for moderate renal impairment (eGFR ≥30 to <60 mL/min) Extensive drug interactions list	300 mg of nirmatrelvir and 100 mg of ritonavir twice-daily for five (5) days	Patients aged 12 years and older	No – per FDA/HHS	**88% effective** in preventing hospitalization or death when started within five (5) days of symptom onset Expected to maintain effectiveness across all variants

THERAPEUTICS OVERVIEW

Please Note: VEKLURY (remdesivir) is commercially available for purchase and is not allocated by the federal government.

Veklury is an antiviral medication that works by inhibiting an enzyme that is essential for SARS-CoV-2 viral replication. The FDA has granted **full approval** for treatment in both hospitalized and non-hospitalized patients who are 12 years of age or older. The FDA has also issued an **EUA** for treatment in both hospitalized and non-hospitalized patients less than 12 years of age.

Please view full prescribing information here, https://www.gilead.com/-/media/files/pdfs/medicines/covid-19/veklury/veklury_pi.pdf and NIH Guidance here.

Generic Name	Also known as	Authorized Indication	Route of Administration	Administration Requirements	Dosing Regimen	Authorized Patient Population	Standing Order?	Efficacy
Remdesivir	**VEKLURY**	**Full FDA Approval** Treatment of COVID-19 for adult and pediatric patients who are hospitalized or not hospitalized and have mild to moderate COVID-19 and are at high risk for progression to severe COVID-19	Intravenous Infusion	May only be administered in settings in which healthcare providers have immediate access to medications to treat severe infusion or hypersensitivity reactions and the ability to activate EMS For non-hospitalized patients, treatment must be initiated as soon as possible after diagnosis and **within seven (7) days of symptom onset**	**For patients weighing 40kg or greater:** 200mg loading dose on Day 1, followed by a once-daily maintenance dose of 100mg from Day 2 **For patients weighing less than 40kg:** 5mg/kg loading dose on Day 1, followed by a once-daily maintenance dose of 2.5mg/kg from Day 2 **Treatment duration**: Hospitalized patients - 5-10 days total, Non-hospitalized patients – three (3) days total	**Full FDA Approval** Adults and pediatric patients (aged 12 years and older and weighing at least 40 kg)	No	**87% effective** at preventing hospitalization/death compared to placebo in non-hospitalized patients considered at high-risk for progression to severe COVID-19 Retains efficacy against Omicron
		EUA Treatment of COVID-19 for pediatric patients who are hospitalized or not hospitalized and have mild to moderate COVID-19 and are at high risk for progression to severe COVID-19				**EUA** Pediatric patients aged 12 years and older weighing 3.5kg to less than 40kg, or pediatric patients **less than 12 years of age** weighing at least 3.5kg		

PROVIDER GUIDANCE AND UPDATED STANDING ORDERS

While our state allocations of COVID-19 therapeutics are expected to remain relatively steady in the coming weeks, supply constraints have begun to ease due to a rapid decline in COVID-19 cases. As such, **NCDHHS has removed the recommendation to prioritize treatment to patients in Tiers 1, 2, or 3 of the NIH treatment panel guidelines.** Providers now can utilize all COVID-19 therapeutics as authorized through the FDA Emergency Use Authorization for each product.

Click here to access the statewide standing order for sotrovimab

New!

Click here to access the statewide standing order for bebtelovimab

Providers are still encouraged to reference the NIH COVID-19 Treatment Panel statement on Product Prioritization for help in determining which COVID-19 therapeutic may be the best option for their patients.

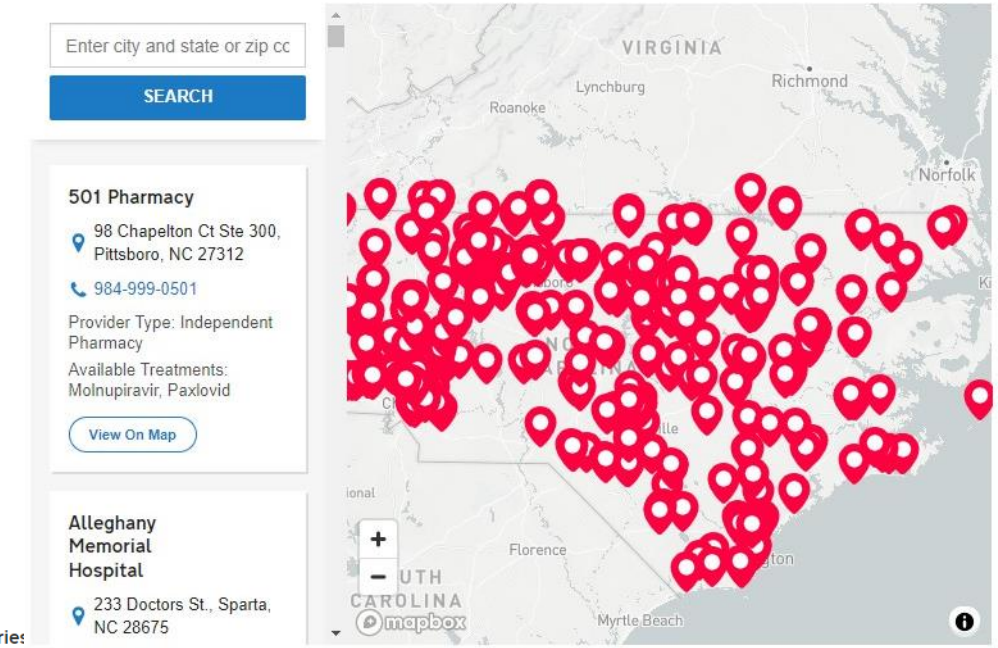
RECIPIENT WAYFINDING

- The ‘Find COVID-19 Treatment’ section on the NC DHHS website includes an updated ‘Site Finder’ tool that enables recipients to:
  - Search for nearby treatment sites
  - Discover available treatments each site offers for administration
  - Find resources to schedule an appointment (phone numbers, websites)

- The ‘Information For Individuals at Higher Risk’ section on the NC DHHS website includes a ‘Site Finder’ tool specifically for EVUSHELD treatment locations.

- There are now **more than 500** therapeutic provider locations statewide.

Site Finder Tool on NC DHHS Website



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Site Name	Available Products	Provider Type	Phone	Address
501 Pharmacy	Molnupiravir, Paxlovid	Independent Pharmacy	984-999-0501	98 Chapelton Ct Ste 300, Pittsboro, NC 27312
Alleghany Memorial Hospital	Sotrovimab, Molnupiravir, Paxlovid	Hospital	336-372-3219	233 Doctors St., Sparta, NC 28675
Americare Pharmacy Consultants	Molnupiravir, Paxlovid	Pharmacy	828-628-3121	1185 Charlotte Highway, Fairview, NC 28730

Q&A